

EFFICACY AND SCIENCE SUPPORT BRANCH

ANTIMICROBIALS DIVISION

EFFICACY REVIEW - I

Reviewed by Ibrahim Barsoum Date 08-07-98

LAN Code 9150-2.998 Michael E. Byrnes

EPA Reg. No. or File Symbol 9150-2

EPA Petition or EUP No. None

Date Division Received 5-6-98

Type Product General Disinfectant & Sanitizer

MRID No(s) 445532-01 and 445532-2

Product Management Team PM 32

Product Name Anthium Dioxide 5%

Company Name International Dioxide Inc.

Submission Purpose:

The registrant has submitted efficacy data to add a new use of the product against Escherichia coli 0157:H7

Type Formulation Liquid

Active Ingredients(s)

Chlorine Dioxide 5%

RISK ASSESSMENT AND SCIENCE SUPPORT BRANCH

ANTIMICROBIAL DIVISION

EFFICACY REVIEW - II

EPA Reg. No. or File Symbol 9150-2

EPA Petition or EUP No. None

Date Division Received 5-6-98

Type Product General Disinfectant & Sanitizer

MRID No(s) 445532-01

Product Management Team PM 32

Product Name Anthium Dioxide 5%

Company Name International Dioxide Inc.

200.0     **Introduction:**

200.1     **Uses:**

General Disinfectant & Sanitizer

200.2     **Background Information:**

The registrant is submitting efficacy data to add a new use of the product against hemorrhagic E.coli 0157:H7.

200.3     **Factors Affecting Amount/Type of Data Required:**

None

201.0     **Data Summary**

None

201.1     **Abstract of Test Reports:**

None

201.2     **Brief Description of Tests:**

1. "AOAC Germicidal and Detergent Sanitizing action of Disinfectants by Andrew Snyder of Viromed Laboratories Inc., Minneapolis, MN, Dated July 7, 1997; MRID no. 445532-1, 445532-2.

201.3     **Data Summaries**

None

201.4     **Other Summarized Results:**

See Recommendations under 202.0.

202.0 Recommendations

202.1 INADEQUATE Data

A. "AOAC Germicidal and Detergent Sanitizing action of Disinfectants" by Andrew Snyder of Viomed Laboratories Inc, Minneapolis, MN dated July 7, 1998, MRID no. 445532-1.

The submitted efficacy data is inadequate & unacceptable for the following reasons:

1. Only one sample was tested instead of the required two samples from two different batches.
2. Product was not also tested at 30 seconds contact time.

B. "AOAC Germicidal and Detergent Sanitizing action of Disinfectants" by Andrew Snyder of Viomed Laboratories Inc, Minneapolis, MN dated July 7, 1998, MRID no. 445532-2.

The submitted efficacy data is not acceptable because the Agency cannot accept claims against specific microorganisms on fruits & vegetables and also for the following reasons:

1. Efficacy was not supported by the data: 99.993% killing instead of the required 99.999%.
2. Also, the data is unacceptable for the reasons mentioned above (MRID # 445532-1).

203.0 Labeling:

1. Labeling claim to disinfect hard non-porous surface against E.coli 0157:H7 is acceptable only after providing data listed above in item 202.1A
2. The Agency cannot accept sanitizing claims against specific microorganisms on fruits & vegetables. Therefore, delete the proposed claim against E. coli 0157:H7 on fruits & vegetables.